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This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.



#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

**Applicant:** 

Kandimalla et al.

Serial No.:

10/694,383

Filed:

October 27, 2003

**Entitled:** 

Modulation of Immunostimulatory Activity of

Immunostimulatory Oligonucleotide Analogs by Positional

**Chemical Changes** 

**Examiner:** 

NA

**Group Art Unit:** 

NA

**Attorney Docket No.:** 

**HYB-005US4 (1006/006)** 

Commissioner for Patents P. O. Box 1450 Alexandria, VA 22313-1450

#### INFORMATION DISCLOSURE STATEMENT

Sir:

Applicants and their attorney are aware of the following publications and information listed on the attached PTO Form 1449, and in accordance with 37 C.F.R. §1.97 hereby submit these publications for the Examiner's consideration.

Applicants state that the current application is a Divisional application claiming priority to U.S. Patent Application Serial No. 09/965,116, filed September 26, 2001. Applicants also state that the references listed on the attached PTO Form 1449 were previously cited in the parent case and therefore copies of the references are not enclosed herewith.

This submission does not represent that a search has been made and does not constitute an admission that the listed documents are material to patentability or that the listed documents are prior art. If it should be determined that any of the listed documents constitute "prior art" under United States law, Applicants reserve the right to present to the Office relevant facts and law regarding the appropriate status of such documents.

This Information Disclosure Statement is being filed before the mailing date of a first Office Action on the merits and is therefore submitted as both timely and proper. Therefore, no fees are believed to be due.

Respectfully submitted,

Date: 2/5/04

Wayne A. Keown Reg. No. 33,923

Keown & Associates 500 West Cummings Park Suite 1200 Woburn, MA 01801 781-938-1805 (Telephone) 781-938-4777 (Facsimile) Subt. Form PTO-1449

INFORMATION DISCLOSURE IN AN APPLICATION

Docket Number

**Application Number** 

HYB-005US4

10/694,383

Applicant

(Use several sheets if necessary)

Kandimalla et al. Filing Date

Sheet 1 OF 2

**Group Art Unit** 10/27/03 NΑ

U.S. Patent Documents						
EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	5,149,798	09/22/92	Agrawal et al.	536	27	

		For	eign Patent Docu	ments	···········		
EXAMINER INITIAL	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
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	WO99/62923		PCT				

	Other Decuments (Institute Automatic District
C1.	Other Documents (Including Author, Title, Date Pertinent Pages, Etc.)
	Khorana et al. (1972) "Studies on Polynucleotides," J. Molec. Blol. 72:209
C2.	Reese (1978) "The Chemical Synthesis of Oligo- and Poly-Nucleotides By The Phosporotriester Approach," Tetrahedron 34:3143-3179
<b>C3</b> .	Beaucage et al. (1981) "Deoxynucleoside Phosphoramidites – A New Class of Key Intermediates for Deoxypolynucleotide Synthesis," Tetrahedron Lett. 22:1859-1862
C4.	Connolly et al. (1984) "Synthesis and Characterization of an Octanucleotide Containing the EcoRi Recognition Sequence With A Phosphorothicate Group At The Cleavage Site," Biochemistry 23:3443
C5.	Agrawal et al. (1987) "Oligodeoxynucleotise Methylphosphonates: Synthesis and Enzymic Degradation," Tetrahedron Lett. 28(31):3539-3542
C6.	Jager et al. (1988) Oligonucleotide N-Alkylphosphoroamidates: Synthesis and Binding to Polynucleotides,"  Biochemistry 27:7237
C7.	Agrawal et al. (1988) "Oligodeoxynucleoside Phosphoroamidates and Phosporothioates As Inhibitors of Human Immunodeficiency Virus, <i>Proc. Natl. Acad. Sci. USA</i> 85:7079-7083
C8.	Zon et al. (1991) "Phosphorothicate Oligorculectides" Oligonuclectides and Analogues: A Practical Approach pp. 87-108
C9.	Kuramoto et al. (1992) "Oligonucleotide Sequences Required For Natural Killer Cell Activation," Jpn. J. Cancer Res. 83:1128-1131
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C14.	Agrawal et al. (1995) "Modified Oligonucleotides as Therapeutic and Diagnostic Agents," Curr.Opin.Biotechnol. 6:12-19
C15.	Krieg et al. (1995) "CpG Motifs in Bacterial DNA Trigger Direct B-Ceti Activation," Nature 371:546-549
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C17.	Liang et al. (1996) "Activation of Human B Cells By Phosphorothicate Oligodeoxynucleotides," J. Clin. Invest. 98:1119-1129
C18.	Zhao et al. (1996) "Effect of Different Chemically Modified Oligodeoxynucleotides on Immune Stimulation," <i>Biochem. Pharm.</i> 51:173-182
C19.	Chu et al. (1997) "CpG Oligodeoxynucleotides Act As Adjuvants That Switch On T Helper 1 (Th1) Immunity," 186 J. Exp. Med. 1623

EXAMINER	DATE CONSIDERED
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EXAMINER: Initial if citation is considered, whether or not citation is in conformance with MPEP § 609: Draw Line through citation if not conformance and not considered. Include copy with next communication to applicant.

P.E Subt. Form P	ГО-1449			Docket Number
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Docket Number	Application Number
HYB-005US4	10/694,383
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Filing Date	Group Art Unit

NA

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	C20.	Dunford et al. (1997) "Antisense 97: Targeting the Molecular Basis of Disease" (Nature Biotechnology) Conference Abstract, pp. 40
	C21.	Sparwasser et al. (1997) "Macrophages Sense Pathogens Via DNA Motifs: Induction of Tumor Necrosis Factor-α-Mediated Shock," 27 Eur. J. Immunol. 1671
	C22.	Zhao et al. (1997) "Pattern and Kinetics of Cytokine Production Following Administration of Phosphorothicate Oligonucleotides in Mice," 7 Antisense Nucleic Acid Drug, Dev. 495
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	C30	Agrawal et al., "Antisense therapeutics", Curr. Opin.Chem.
		Biol., 2:519-528, 1998.
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		<u>  Stability Studies", Biorg. &amp; Med.Chem., 6:827-832, 1996.  </u>
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		Bioorganic & Medicinal Chemistry, 9:807-813, 2001.
	C35	International Search Report (PCT APP. No. PCT/USO1/30137).
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